

## 10734 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

## EXHIBIT B

Drug  
Recalls

The following data have been compiled from the Federal Food and Drug Administration Weekly Recall Reports covering the period October 18, 1973, to December 12, 1973. Pharmacists and others possessing drug inventories are reminded to check their stock again; be certain that they do not have any of the products on the list. Anyone who has additional facts on any of the listed recalls which he feels will assist in completing the recall is urged to send such data to the editor of this JOURNAL.

| Product                                                                                                                           | Manufacturer or Distributor                                                                | Lot Number                                                                                                                                                            | Quantity                                | Recall Class | Recall Reason                                                    | Product Distribution |
|-----------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|--------------|------------------------------------------------------------------|----------------------|
| Afrodex Capsules (methyltestosterone 5 mg, yohimbine 5 mg, nuxvomica extract 5 mg), 100's, 500's and 1,000's                      | ICN Pharmaceuticals (Covina, Calif.)<br>Private Formulas (St. Louis, Mo.)                  | All lots                                                                                                                                                              | 1,300,000 capsules                      | II           | No approved NDA                                                  | National             |
| APC Tablets (aspirin 3.5 gr, phenacetin 2.5 gr, caffeine 0.5 gr), 100's and 1,000's                                               | Linden Labs (Los Angeles, Calif.)<br>Vitamin Specialties (Brisbane, Calif.)                | 231208                                                                                                                                                                | Unknown                                 | III          | Content uniformity                                               | California           |
| Atropine sulfate injectable 0.01 gr, 1 ml ampules                                                                                 | Harvey Laboratories (Philadelphia, Pa.)                                                    | 0522                                                                                                                                                                  | 1,500 ampules                           | III          | Subpotency                                                       | National             |
| AUS-tect for CEP Test (hepatitis associated antibody-anti-Australia antigen) 1 ml and 5 ml vials                                  | Abbott Labs (Los Angeles, Calif.)                                                          | 1 ml vials<br>28-013-BW<br>antibody lot<br>Z730330<br>5 ml vials<br>28-051-BW<br>antibody lot<br>Z730428                                                              | 800 vials                               | II           | Loss of potency                                                  | National             |
| Celebenin (sodium methicillin for injection), 1 g, 4 g, and 6 g vials                                                             | Beecham-Massengill Pharmaceuticals (Piscataway, N.J.)                                      | 1 g vials<br>A0119RH<br>A0209RN<br>A0259RP<br>A0309SA<br>A0319SA<br>A0349SA<br>A0359SA<br>4 g vials<br>A0099RH<br>A0199RN<br>A0219RN<br>6 g vials<br>A0299SA<br>AB030 | 600 vials<br>predominantly<br>lot AB030 | II           | Pyrogens                                                         | National             |
| Digitoxin tablets 0.2 mg, 1,000's and 5,000's                                                                                     | Zemmer Co. (Oakmont, Pa.)                                                                  | 389190                                                                                                                                                                | 35,000 tablets                          | II           | Content uniformity                                               | National             |
| H P Acthar Gel (repository corticotropin injection 40 USP units per ml) 1 ml and 5 ml vials                                       | Armour Pharmaceutical Co. (Kankakee, Ill.)<br>National Drug Co. (Cincinnati, Ohio)         | J407                                                                                                                                                                  | Unknown                                 | II           | Subpotency                                                       | National             |
| Insulin syringe with needle (disposable), 1 cc, 100 unit                                                                          | Sherwood Medical Industries (St. Louis, Mo.)                                               | 502195                                                                                                                                                                | Unknown                                 | II           | Cartons of 100/100 unit labeled as 100/40/80 units               | National             |
| Kidneez (phenazopyridine 100 mg), 30's                                                                                            | Edward J. Moore Sons (Long Island City, N.Y.)                                              | All lots                                                                                                                                                              | 120,000 tablets                         | II           | Label does not bear prescription legend                          | National             |
| Mercurhydrin Injection (meralluride sodium 30 mg, theophylline 48 mg per ml), 1 ml and 2 ml ampules, 10 cc multiple dose vials    | Lakezide Laboratories (Milwaukee, Wisc.)                                                   | All lots                                                                                                                                                              | 8,000 units                             | II           | Precipitate                                                      | National             |
| Otos Mosan otic solution (0.5 mg sulfathiazole, 60 mg sodium propionate, 125 mg urea per ml), 15 ml dropper bottles               | Ayerst Labs (New York, N.Y.)                                                               | All lots                                                                                                                                                              | 6,000 bottles                           | II           | Drug efficacy study implementation                               | National             |
| Secobarbital sodium capsules 1.5 gr, 100's and 1,000's                                                                            | Interstate Drug Exchange (Plainview, N.Y.)<br>Columbia Pharmaceuticals (Garden City, N.Y.) | 2970                                                                                                                                                                  | Unknown                                 | III          | Subpotency                                                       | National             |
| Sodium Salicylate and Iodide with Colchicine, No. 1 (sodium salicylate 1 g, sodium iodide 1 g, colchicine 0.66 mg), 20 ml ampules | Upjohn Co. (Kalamazoo, Mich.)                                                              | All lots                                                                                                                                                              | 1,000 ampules                           | II           | Lack of evidence that the drug combination is safe and effective | National             |

## FDA definitions for recall classes:

**Class I Recall:**—This is an emergency situation involving the removal from the market of products in which the consequences are immediate or long-range, life-threatening and involve a direct cause-effect relationship.

**Class II Recall:**—This is a priority situation in which the consequences may be immediate or long-range and possibly or potentially life-threatening or hazardous to health.

**Class III Recall:**—This is a routine situation in which the consequences to life (if any) are remote or non-existent.